
EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations, which extend to Scotland only, implement Articles 9 and 11 of Council Directive [89/398/EEC](#) on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, (O.J. No. L 186, 30.6.89, p.27), as last amended by Regulation [\(EC\) No. 1882/2003](#) (O.J. No. L 284, 31.10.03, p.1).

The Regulations concern foods which, owing to their special composition or manufacturing process, are clearly distinguishable from foods for normal consumption and which are marketed as suitable for categories of consumers with disturbed digestive processes or metabolism or in a special physiological condition, or for infants or young children in good health, but which are neither covered nor to be covered by other Directives on specific types of foodstuffs for particular nutritional uses (the definition of “PNU food” in regulation 2(1) refers).

These Regulations—

- (a) prohibit the sale of such products unless the requirements of Article 9 of the Directive (notification to competent authorities of such products) have been complied with (regulation 3); and
- (b) enable the Food Standards Agency by written declaration to suspend or restrict trade in products intended for a particular nutritional use where it has detailed grounds for establishing that the product does not comply with Article 1(2) of the Directive (requirements for foodstuffs for particular nutritional uses) or endangers human health (regulation 4).

Enforcement responsibilities, offences and penalties and application of provisions of the Food Safety Act 1990 are set out in regulations 5, 6 and 7 of these Regulations.

These Regulations also revoke the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 (regulation 8).

Labelling provisions of the Directive are implemented in the Food Labelling Regulations 1996 (S.I.1996/1499).

A full regulatory impact assessment of the effect that this instrument will have on the costs to business has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.